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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/782,075

02/19/2004

Sean D. Monahan

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MIRUS CORPORATION
505 SOUTH ROSA RD
MADISON, WI 53719

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

06/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/782,075	Applicant(s) MONAHAN ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-10,13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 10/08/2007 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 07/11/2007 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 10/08/2007, claims 1, 4-10 and 13-14 are pending in the application. Applicant has canceled claims 2-3 and 11-12.

Terminal Disclaimer

The terminal disclaimer filed on 03/19/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of copending Application No. 10/780,48 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Declaration

The declarations filed on 03/19/2008 under 37 CFR 1.132 are considered but are moot given the rejection of claims as anticipated or obvious over Wolff et al. (US 2001/0044417) have been withdrawn.

Response to Applicant's Arguments

Re: Double Patenting

The rejection of claims 1, 4-10, 13 and 14 as provisionally rejected under the judicially created doctrine of double patenting over claims 1, 3, 6-7, 10-18 of copending Application No. 10/780,484 is withdrawn due to the filing and approval of a terminal disclaimer.

Re: Claim Rejections - 35 USC § 102

The rejection of claims 1, 5, 13 and 14 under 35 U.S.C. 102(b) as being anticipated by Wolff et al. (US 2001/0044417) is withdrawn.

The rejection of claims 1, 4-6, 10 and 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewis et al. (US 2003/0143204) is maintained for the reasons of record in the previous Office action mailed 12/31/2007.

Applicant's arguments filed 03/19/2008 have been fully considered but they are not persuasive. Applicant argues Lewis et al. does not teach post-synthetic modification of RNA, attachment of a group to siRNA via a labile bond or attachment of a function group that enhances interaction of the RNA with a transfection reagent.

Applicant's arguments are not convincing. Lewis et al. in paragraph 0042 do in fact teach antisense compounds and siRNA can be further modified with 2'-modifications. Also it must be noted that the claims are not limited to a "post-synthetic

modification of an RNA", the claims only require a modified RNA that consists of a functional group "post-synthetically linked".

Further, Lewis et al. teach the functional group are attached to the RNA via labile bonds that can be selectively broken and dissociated to provide an active inhibitor in the cell (see paragraphs 0120-0128). Because Lewis et al. contemplates RNA as antisense or siRNA, Lewis et al. teach attachment of functional groups via labile bonds to siRNA.

In response to Applicant's argument that Lewis et al. do not teach attachment of a function group that enhances interaction of the RNA with a transfection reagent, it must noted that the instant specification on page 3 teach that "Hydrophobic modification of the siRNA allows hydrophobic interaction of the siRNA with the transfection agent. Therefore, any functional group that is hydrophobic would enhance the interaction of the RNA with the transfection reagent and instantly disclosed. Lewis et al. teach functional groups such as lipids, fatty acids and cholesterol, which are considered hydrophobic and therefore would enhance the interaction of the RNA with the transfection reagent.

Thus, the rejection is maintained.

Re: Claim Rejections - 35 USC § 103

The rejection of claims 1, 4-9, 13 and 14 under 35 U.S.C. 103(a) as being obvious over Hughes et al. (U.S. Patent No. 6,169,078), Manoharan, M. (Biochimica et Biophysica Acta 1489, 1999: 117-130) and Goldsborough (of record PTO Form 892 11/29/2005) is withdrawn.

The rejection of claims 1, 4-6, 10, 13 and 14 under 35 U.S.C. 103(a) as being obvious over Wolff et al. (US 2001/0044417), Manoharan, M. (Biochimica et Biophysica Acta 1489, 1999: 117-130) and Tuschl et al. (of record PTO Form 892 11/29/2005) is withdrawn.

The rejection of claims 1, 4-10, 13 and 14 under 35 U.S.C. 103(a) as being obvious over Fosnaugh et al. (US 2003/0143732), Manoharan, M. (Biochimica et Biophysica Acta 1489, 1999: 117-130) and Goldsborough (of record PTO Form 892 11/29/2005) is maintained for the reasons of record in the Office action mailed 12/31/2007.

Applicant's arguments filed 03/19/2008 have been fully considered but they are not persuasive. Applicant argues Fosnaugh et al. do not teach pairing a functional group with a transfection agent such that the functional group enhances interaction of the siRNA with a transfection reagent. It appears Applicant is arguing that the chemical modification of the siRNA is responsible for enhancing the interaction with a transfection reagent. The claims are drawn to a modified RNA linked to a functional group wherein "said functional group enhances the interaction of said RNA with said transfection reagent" and do not require the modification to be responsible for enhancing the interaction of the RNA with the transfection reagent as argued by Applicant. It must be noted that the instant specification on page 3 teaches that "Hydrophobic modification of the siRNA allows hydrophobic interaction of the siRNA with the transfection agent. Therefore, any functional group that is hydrophobic would enhance the interaction of the

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RNA with the transfection reagent. Fosnaugh et al. teach the functional groups can be lipids, which are hydrophobic and teach the conjugate can be mixed with transfection reagents for delivery to cells. Therefore, the attachment of the lipid functional group would enhance the interaction of the RNA with the transfection reagent.

Thus, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

KC

Examiner AU1635

/Sean R McGarry/

Primary Examiner, Art Unit 1635